EXHIBIT A

MARKETING NEURONTIN

Expert Report of Charles King III

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d. whether Pfizer's off-label marketing of Neurontin indirectly influenced all prescribing physicians of Neurontin.

C. Materials Relied Upon

15. In reaching my conclusions, I have relied upon the materials identified in Attachment B and throughout this report. I have also reviewed the results of analyses performed by Keith Altman, Finkelstein & Partners, LLP, and carried out under my direction of data requested from counsel.[29] My opinions are also based on my experience as an academic researcher in the pharmaceutical industry and my expertise as an economist specializing in marketing and industrial organization. I reserve the right to supplement my analyses and opinions in light of additional documents, data, expert reports, or testimony that may subsequently become available. I also reserve the right to prepare and use visual aids in connection with my testimony at trial.

IV. The Success of the Neurontin Off-Label Strategy

A. Growth in Neurontin Off-Label Prescriptions

16. Warner-Lambert estimated that the "ultimate" sales potential for Neurontin over the life of its patent was only $500 million because of the limited adjunctive use for which it had been approved.[30] To expand the market for Neurontin, Warner-Lambert developed a "publication strategy."[31] Its goal was "to disseminate the information [about Neurontin's potential use for psychiatric disorders, including bipolar and mood and anxiety disorders] as widely as possible through the world's medical literature"[32] as a means of generating excitement in the market and stimulating off-label prescriptions despite the lack of FDA approval.[33] Warner-Lambert calculated that this strategy would avoid

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[29] Data requested from plaintiffs council. Data computations performed by Keith Altman, Finkelstein & Partners, LLP,under my direction.

[30] See Memorandum from Walker to Laesecke, Pierce and Ulrich, 5/18/94, V090268.

[31] For an overview of the public education strategy, see generally Sentencing Memorandum of the United States and Steinman et al. article.

[32] *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp.2d 39 (D. Mass. 2001), Exhibit 171. [Inner office memorandum from Atul Pande to John Boris, re: "Gabapentin Approvals", and handwritten response]; 28 March 1995: X029227.

[33] *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp.2d 39 (D. Mass. 2001), Exhibit 26. Marketing Assessments – Neurontin in Neuropathic Pain and Spasticity [and cover letter]; 24 July 1995: WL 07520 – 07547 and Exhibit 31 [Parke-Davis memo from John Boris to "Distribution," re: "Marketing Assessments – Neurontin in Migraine," and cover letter]; 31 July 1996: V 082736 – 082761.

the new medicines, products and therapies;[58] providing free drug samples; answering physicians' questions and maintaining goodwill. The distribution of free drug samples ("sampling") also targets doctors directly. Sampling is designed to increase sales by building a physician's personal experience with the drug and increasing his or her confidence in prescribing it.[59] Medical education events, such as symposia, conferences, and lectures, have a substantial influence on prescribing behavior.[60] Pharmaceutical companies subsidize and sponsor these programs as one component of their overall promotion strategy.[61]

F. Marketing Neurontin for Off-Label Uses

31. Since the drug company educates the medical profession and the public about its drugs and the conditions they treat, this creates an inherent conflict of interest between selling drugs and evaluating them. Most of these medical educational activities are directed towards doctors. In the case of Neurontin, it was crucial for Warner-Lambert and allegedly Pfizer to maintain that these expenditures were for education, not promotion, so that it could evade legal constraints on its marketing activities.[62] Drug company sponsorship does not mean that research is necessarily biased, but in the case of Neurontin, the drug company allegedly influenced the research, subverted the scientific process, and biased the sources that doctors relied upon for unbiased information.[63]

G. Doctors Depend on the Integrity of the Scientific Process for Unbiased Information About Drugs

32. Doctors depend on the integrity of the scientific process for accurate and reliable information about the drugs they prescribe. Warner-Lambert and Pfizer allegedly subverted the scientific process in two ways: by what they did and by what they did not do. Warner-Lambert and Pfizer allegedly promoted off-label uses of Neurontin by making false claims about its uses and efficacy. Warner-

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[58] See, e.g., D. Dogramatzis, *Pharmaceutical Marketing: A Practical Guide*, Colorado: IHS Health Group, 2002.

[59] Schweitzer, *op. cit.*, p. 49

[60] "One study of prescribing decisions by general physicians found that seminars, conferences, and lectures organized by pharmaceutical companies had more influence than advertisements, promotional material (e.g., samples, calendars, or diaries), or direct mail. Moreover, many of the doctors surveyed did not interpret such 'educational' activity as promotion (Pitt and Nel 1988)." Schweitzer, *op. cit.*, p. 52.

[61] Schweitzer, *op. cit.*, p. 52

[62] Sentencing Memorandum of the United States, pp 40-42; Steinman et al. (2006), pp. 286-288.

[63] See, e.g., Sentencing Memorandum of the United States; Steinman et al. (2006).

Lambert and Pfizer allegedly failed to disclose or omitted information about Neurontin's lack of efficacy and its side effects. Both these actions would have affected the prescribing habits of physicians.

H. How Drug Company Promotion Influences Doctors

33. The effect of drug promotion on physician beliefs, knowledge, and self-reported behavior has been widely studied.[64] Although doctors generally do perceive pharmaceutical marketing to be effective, they do not appear to recognize their own susceptibility to commercial influences.[65] Academic studies suggest that inaccurate, incorrect or misleading information about drugs may be frequently conveyed in promotional settings,[66] that doctors do not consistently distinguish between correct and incorrect information,[67] and that the perceived –

[64] See footnotes 65 - 73 and E. Clayton, "'Tis Always the Season for Giving," CALPIRG Report, September 2004; Editorial Staff, "Pharmaceutical Marketing to Physicians: Free Gifts Carry a High Price," *American Medical News*, 10 June 2002; A. Wazana, "Physicians and the Pharmaceutical Industry," *The Journal of the American Medical Association,* 283:373-380, 2000; A. Fugh-Berman, "The Corporate Coauthor," *Journal of General Internal Medicine,* 20(6):546-8, June 2005.

[65] J. Avorn, M. Chen, and R. Hartley, "Scientific Versus Commercial Sources of Influence on the Prescribing Behavior of Physicians," *American Journal of Medicine,* 73 (1), 4–8, 1982.

[66] M. Bowman and D. Pearle, "Changes in Drug Prescribing Patterns Related to Commercial Company Funding of Continuing Medical Education," *Journal of Continuing Education in the Health Professions* 8:13–20, 1988; M. G. Ziegler, P. Lew, B. C. Singer (1995) "The Accuracy of Drug Information from Star Pharmaceutical Sales Representatives," JAMA 273: 1296-1298; E. Hemminki (1997), "Content Analysis of Drug-Detailing by Pharmaceutical Representatives," Med Educ 11:210-215; D. Stryer and L.A. Bero, "Characteristics of Materials Distributed by Drug Companies. An Evaluation of Appropriateness," J. Gen Intern Med 11: 575-583; H.A. Waxman, (2005), "Memorandum to Democratic Members of House Government Reform Committee: a Marketing of Vioxx to Physicians," available: HTTP://www.democrats.reform.house.gov/documents/20050505114932-41272.pdf; E.E. Roughead, A. L. Gilbert and K.J. Harvey (1998), "Self-Regulatory Codes of Conduct: Are They Effective in Controlling Pharmaceutical Representatives' Presentations to General Medical Practitioners?" Int J Health Serv 28:269-279; J. Lexchin (1997), "What Information do Physicians Receive from Pharmaceutical Representatives?" Can Fam Physician 43: 941-945.

[67] M. G. Ziegler, P. Lew, B. C. Singer (1995) "The Accuracy of Drug Information from Star Pharmaceutical Sales Representatives," JAMA 273: 1296-1298; D. Stryer and L.A. Bero, "Characteristics of Materials Distributed by Drug Companies. An Evaluation of Appropriateness," J. Gen Intern Med 11: 575-583; A. E. Shaughnessy, D. C. Slawson and J.H. Bennett (1994), "Separating the Wheat from the Chaff: Identifying Fallacies in Pharmaceutical Promotion," J Gen Intern Med 9: 563-568; W. Molloy, D. Strand, G. Guyatt et al. (2002), "Assessing the Quality of Drug Detailing," Journal of Clinical Epidemiology 55:825-832.

launch.[82] Warner-Lambert began seeking FDA approval for some indications, such as monotherapy for seizures, pediatric adjunctive treatment for seizures, and post-herpetic neuralgia. But FDA approval typically required expensive and time-consuming, randomized controlled double-blind clinical trials, which always carry the risk of demonstrating a negative (or inconclusive) effect. Despite conducting clinical trials in the United States and abroad, neither Warner-Lambert nor later Pfizer was ever to receive approval for Neurontin monotherapy indications.[83]

40. After evaluating the potential markets for other clinical uses, such as treatment of bipolar disorder, painful diabetic neuralgia, and chronic pain,[84] Warner-Lambert calculated that seeking FDA approval would not be worthwhile because of the expense of clinical trials, the short remaining patent life for Neurontin and the potential adverse impact on the sales of a new drug that Warner-Lambert was developing.[85] Warner-Lambert decided to promote off-label uses of Neurontin even though off-label promotion is expressly prohibited by the FDA.[86]

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[82] Information, ¶¶ 11-13; Sentencing Memorandum of the United States, pp. 13-17. See, e.g., Deposition of John M. Knoop, *United States v. Pfizer Inc., and Parke-Davis*, Case No. 96-11651-PBS, September 25, 2002 (Knoop Deposition), pp. 27-28 and 225-255; Memorandum from Mi Dong to Neurontin (Anticonvulsant) Development Team of 11/7/94, X029017-25; Memorandum from Mi Dong to Neurontin Development Team of 1/19/95, X028970-75 at pp. X028974-75; Memorandum from Mi Dong to Neurontin Development Team of 2/28/95, X028965-69 at X208969; Deposition of John Boris, *United States v. Pfizer Inc. and Parke-Davis*, Case No. 96-11651-PBS, September 16, 2002 (Boris Deposition), pp. 17-21; and Marketing Assessment: Neurontin in Psychiatric Disorders of 5/18/95, V090836-77.

[83] Marino deposition, pp. 69-70.

[84] Information ¶¶ 11-16. See also: *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp.2d 39 (D. Mass. 2001), Exhibit 27. [Parke-Davis memo from Francie Kivel to "Distribution," re: "Minutes from August 9, 1995 Neurontin Indications Decision Analysis Group Meeting"]; 29 August 1995: V049269-V049274 at 71. ("The indications to be investigated in the first phase of this analysis will be neuropathic pain, social phobia, panic, and bipolar disorders. ALS and spasticity will be examined subsequently.")

[85] The new drug was pregabalin. See, e.g., Memorandum from Mi Dong to Neurontin Anticonvulsant Development Team of 3/16/95, X028957-62 at p. X028961; Memorandum from J. Pieroni to Anton, Brandner, Cadre, Evans, Gemelli, Montgomery, and Summers of 3/22/95, V086787-92 at V086789; Interoffice Memorandum from Pande to Boris of 3/23/95, X029226; Cover letter from Brandicourt to Development Team of 7/31/95 with attached Marketing Assessment: Neurontin in Neuropathic Pain and Spasticity of 7/24/95, WL 07524-47 at WL 07524; Memorandum from Boris to Neurontin Pharmaceutical Sector Marketing Group of 7/31/96, V082736-61 at V082737; Marketing Assessment: Neurontin in Psychiatric Disorders of 5/18/95, V090836-77; and Memorandum from Francie Kivel to J. Boris, O. Brandicourt, E. Guerrero, J. Knoop, L. Magnus-Miller, and L. Perlow, October 26, 1995, V053848-77 at V053853.

[86] Information, ¶¶ 5, 19, 23-4, 27-8, and 34. See, e.g., Knoop Deposition, p. 35; and Deposition of James Parker, *United States v. Pfizer Inc., and Parke-Davis*, Case No. 96-11651-PBS, May 17, 2002 (Parker Deposition), pp. 136-37.